

We Claim:

1. A method of detecting the presence of a target BS322 polynucleotide
5 in a test sample, said method comprising:

- (a) contacting the test sample with at least one BS322-specific polynucleotide or complement thereof, wherein said BS322-specific polynucleotide has at least 50% identity with a polynucleotide selected from the group consisting of SEQUENCE ID NOS 1-9, and fragments or complements thereof; and
10 (b) detecting the presence of target BS322 polynucleotides from the test sample which bind to said BS322-specific polynucleotide.

2. The method of claim 1, wherein said target BS322 polynucleotide is attached to a solid phase prior to performing step (a).
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3. The method of claim 1, wherein said BS322-specific polynucleotide is attached to a solid phase prior to performing step (a).

4. A method for detecting BS322 mRNA in a test sample, said method
20 comprising:

- (a) performing reverse transcription on said sample using at least one primer in order to produce cDNA;
(b) amplifying the cDNA obtained from step (a) using BS322 oligonucleotides as sense and antisense primers to obtain BS322 amplicon; and
25 (c) detecting the presence of said BS322 amplicon, wherein the BS322 oligonucleotides utilized in steps (a) and (b) have at least 50% identity with a sequence selected from the group consisting of SEQUENCE ID NOS 1-9, and fragments or complements thereof.

5. The method of claim 4, wherein said test sample is reacted with a solid phase prior to performing one of steps (a), (b), or (c).
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6. The method of claim 4, wherein said detection step comprises utilizing a detectable label capable of generating a measurable signal.

5 7. A method of detecting a target BS322 polynucleotide in a test sample suspected of containing said target polynucleotide, comprising:

(a) contacting the test sample with at least one BS322 oligonucleotide as a sense primer and with at least one BS322 oligonucleotide as an anti-sense primer and amplifying to obtain a first stage reaction product;

10 (b) contacting said first stage reaction product with at least one other BS322 oligonucleotide to obtain a second stage reaction product, with the proviso that the other BS322 oligonucleotide is located 3' to the BS322 oligonucleotides utilized in step (a) and is complementary to said first stage reaction product; and

15 (c) detecting said second stage reaction product as an indication of the presence of the target BS322 polynucleotide, wherein the BS322 oligonucleotides utilized in steps (a) and (b) have at least 50% identity with a sequence selected from the group consisting SEQUENCE ID NOS 1-9, and fragments or complements thereof.

20 8. The method of claim 7, wherein said test sample is reacted with a solid phase prior to performing one of steps (a), (b), or (c).

9. The method of claim 7, wherein said detection step comprises utilizing a detectable label capable of generating a measurable signal.

25 10. The method of claim 9, wherein said detectable label is reacted to a solid phase.

30 11. A test kit useful for detecting BS322 polynucleotide in a test sample, said test kit comprising a container containing at least one BS322 polynucleotide having at least 50% identity with a sequence selected from the group consisting SEQUENCE ID NOS 1-9, and fragments or complements thereof.

12. A purified polynucleotide derived from a BS322 nucleic acid molecule, wherein said polynucleotide has at least 50% identity with a sequence selected from the group consisting of SEQUENCE ID NOS 1-9, and fragments or complements thereof.

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13. The polynucleotide of claim 12, wherein said polynucleotide hybridizes selectively to a BS322 nucleic acid sequence.

14. The polynucleotide of claim 12, wherein said polynucleotide has an overall length of about 20 to about 50 nucleotides.

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15. The polynucleotide of claim 12, wherein said polynucleotide has an overall length of about 10 to about 25 nucleotides.

16. The polynucleotide of claim 12, wherein said polynucleotide is produced by recombinant techniques.

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17. The polynucleotide of claim 12, wherein said polynucleotide is produced by synthetic techniques.

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18. The polynucleotide of claim 12, wherein said polynucleotide comprises a sequence encoding at least one BS322 epitope.

19. The polynucleotide of claim 12, wherein said polynucleotide is attached to a solid phase.

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20. The polynucleotide of claim 19, wherein said solid phase comprises an array of polynucleotide molecules attached thereto.

21. A recombinant expression system comprising a nucleic acid sequence that includes an open reading frame derived from a BS322 polynucleotide, wherein said open reading frame is operably linked to a control sequence compatible with a desired host, and said nucleic acid sequence has at least 50% identity with a sequence

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selected from the group consisting of SEQUENCE ID NOS 1-9, and fragments or complements thereof.

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22. A cell transfected with the recombinant expression system of claim 21.

23. A BS322 polypeptide having at least 50% identity with an amino acid sequence selected from the group consisting of SEQUENCE ID NO 24, SEQUENCE ID NO 25, SEQUENCE ID NO 26, SEQUENCE ID NO 27, SEQUENCE ID NO 28, and fragments thereof.

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24. The polypeptide of claim 23, wherein said polypeptide is produced by recombinant techniques.

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25. The polypeptide of claim 23, wherein said polypeptide is produced by synthetic techniques.

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26. A specific binding molecule which binds to at least one BS322 epitope, wherein said BS322 epitope is derived from an amino acid sequence having at least 50% identity with an amino acid sequence selected from the group consisting of SEQUENCE ID NO 24, SEQUENCE ID NO 25, SEQUENCE ID NO 26, SEQUENCE ID NO 27, SEQUENCE ID NO 28, and fragments thereof.

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27. The specific binding molecule of claim 26, wherein said molecule is an antibody molecule.

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28. A test kit for determining the presence of BS322 antigen or anti-BS322 antibody in a test sample, said kit comprising a container containing a BS322 polypeptide having at least 50% identity with an amino acid sequence selected from the group consisting of SEQUENCE ID NO 24, SEQUENCE ID NO 25, SEQUENCE ID NO 26, SEQUENCE ID NO 27, SEQUENCE ID NO 28, and fragments thereof.

29. The test kit of claim 28, wherein said BS322 polypeptide is attached to a solid phase.

30. A test kit for determining the presence of BS322 antigen in a test sample, said kit comprising a container containing a specific binding molecule which binds to a BS322 antigen having at least one BS322 epitope.

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31. The kit of claim 30, wherein said specific binding molecule is attached to a solid phase.

32. A method for producing a polypeptide comprising at least one BS322 epitope, said method comprising incubating host cells that have been transfected with an expression vector containing a polynucleotide sequence encoding a polypeptide, wherein said polypeptide comprises an amino acid sequence having at least 50% identity with an amino acid sequence selected from the group consisting of SEQUENCE ID NO 24, SEQUENCE ID NO 25, SEQUENCE ID NO 26, SEQUENCE ID NO 27, SEQUENCE ID NO 28, and fragments thereof.

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33. A method for detecting BS322 antigen in a test sample suspected of containing said BS322 antigen, comprising:

(a) contacting the test sample with a specific binding molecule which binds to at least one epitope of a BS322 antigen selected from the group consisting of SEQUENCE ID NO 24, SEQUENCE ID NO 25, SEQUENCE ID NO 26, SEQUENCE ID NO 27, SEQUENCE ID NO 28, and fragments thereof, wherein said contacting is performed for a time and under conditions sufficient for the formation of binding molecule/antigen complexes; and

(b) detecting the presence of said complexes as an indication of the presence of said BS322 antigen.

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34. The method of claim 33, wherein said specific binding molecule is an antibody molecule or a fragment thereof.

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35. The method of claim 33, wherein said specific binding molecule is attached to a solid phase.

36. A method for detecting the presence of antibodies specific for a BS322 antigen in a test sample suspected of containing such antibodies, said method comprising:

- 5 (a) contacting the test sample with a BS322 polypeptide, wherein said BS322 polypeptide contains at least one BS322 epitope derived from an amino acid sequence having at least 50% identity with an amino acid sequence selected from the group consisting of SEQUENCE ID NO 24, SEQUENCE ID NO 25, SEQUENCE ID NO 26, SEQUENCE ID NO 27, SEQUENCE ID NO 28, and fragments thereof, and further wherein said contacting is performed for a time and under conditions sufficient
10 to allow antigen/antibody complexes to form; and
- (b) detecting the presence of said complexes as an indication of the presence of antibodies specific for a BS322 antigen.

37. The method of claim 36, wherein said BS322 polypeptide is attached
15 to a solid phase.

38. A cell transfected with a nucleic acid sequence encoding at least one BS322 epitope, wherein said nucleic acid sequence is selected from the group consisting of SEQUENCE ID NOS 1-9, and fragments or complements thereof.
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39. A method for producing antibodies which specifically bind to BS322 antigen, comprising administering to an individual an isolated immunogenic polypeptide or fragment thereof in an amount sufficient to elicit an immune response, wherein said immunogenic polypeptide comprises at least one BS322 epitope and has
25 at least 50% identity with a sequence selected from the group consisting of SEQUENCE ID NO 24, SEQUENCE ID NO 25, SEQUENCE ID NO 26, SEQUENCE ID NO 27, SEQUENCE ID NO 28, and fragments thereof.

40. A method for producing antibodies which specifically bind to BS322
30 antigen, comprising administering to an individual a plasmid comprising a sequence which encodes at least one BS322 epitope derived from a polypeptide having an amino acid sequence selected from the group consisting of SEQUENCE ID NO 24,

SEQUENCE ID NO 25, SEQUENCE ID NO 26, SEQUENCE ID NO 27,
SEQUENCE ID NO 28, and fragments thereof.

5 41. The test kit of claim 11 further comprising a container with tools useful
for collection of said sample, wherein the tools are selected from the group consisting
of lancets, absorbent paper, cloth, swabs and cups.

10 42. The test kit of claim 28 further comprising a container with tools useful
for collection of said sample, wherein the tools are selected from the group consisting
of lancets, absorbent paper, cloth, swabs and cups.

15 43. The test kit of claim 30 further comprising a container with tools useful
for collection of said sample, wherein the tools are selected from the group consisting
of lancets, absorbent paper, cloth, swabs and cups.

20 44. The test kit of claim 30, wherein said specific binding molecule is an
antibody or fragment thereof.

25 45. The polynucleotide of claim 12, wherein said polynucleotide codes for
a BS322 protein which comprises an amino acid sequence having at least 50%
identity to SEQUENCE ID NO 24 or SEQUENCE ID NO 25.

30 46. The polynucleotide of claim 12, wherein said polynucleotide comprises
DNA having at least 50% identity with SEQUENCE ID NO 8 or SEQUENCE ID NO
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 47. The method of claim 1, wherein the presence of said target BS322
polynucleotide in the test sample is indicative of breast disease.

30 48. The method of claim 4, wherein the presence of said amplicon is
indicative of breast disease.

49. The method of claim 7, wherein the presence of said second stage reaction product is indicative of breast disease.

50. The method of claim 33, wherein detection of said complexes is
5 indicative of breast disease.

51. The method of claim 36, wherein detection of said complexes is indicative of breast disease.

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